MAY - 1 2012

510K SUMMARY

510K Number:	**k111925**
Submitted By:	Psychemedics Corporation 5832 Uplander Way Culver City, CA 90230 TEL: 310 216 7776 FAX: 310 216 6662
Submission Contact:	Virginia Hill
Date Prepared:	April 25, 2012
Device Trade Name:	Psychemedics Microplate EIA for Cocaine in Hair
Predicate Device:	Psychemedics Cocaine Assay, k010868
Product Code:	JXO
Device Classification/Name:	21 CFR 862.3250, Enzyme Immunoassay, Cocaine; Classification II;
Intended Use:	The Psychemedics Microplate EIA for Cocaine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cocaine in human head and body hair samples using a cocaine calibrator at 5 ng /10 mg hair cutoff for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use only and not for sale to anyone. The Psychemedics EIA Cocaine Assay provides only a preliminary analytical test result. To obtain a quantitative analytical result or to confirm positive results, a more specific alternate chemical method (e.g. GC/MS) must be used. Clinical consideration and professional judgment should be applied to the interpretation of any drug-of-abuse test result.
Assay Description:	The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Cocaine. The drug is recovered from the hair using a patented method (U.S. Patent #8,084,215). The screening portion of the test system consists of (1) microplate wells coated with multiple drugs including benzoylecgonine conjugated to bovine serum albumin (BSA) (patent pending), monoclonal mouse anti-cocaine, goat anti-mouse secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to acidify the final reaction, and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.
Sample Collection:	A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into

place within the foil. The hair sample crimped within the foil is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory.

Materials required: Hair sample collection kit, Microplate EIA for Cocaine, Microplate washer and reader, LC/MS/MS for confirmation.

Comparison of Psychemedics Microplate EIA for Cocaine with Psychemedics RIA Assay for Cocaine

Item	Device	Predicate
Indications for Use	The Psychemedics Microplate EIA for Cocaine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cocaine in human head and body hair samples using a cocaine calibrator at 5 ng /10 mg hair cutoff for the purpose of identifying cocaine use. This product is intended exclusively for in-house professional use only and not for sale to anyone. The test is not intended for over-the-counter sale to non-professionals. The Psychemedics EIA Cocaine Assay provides only a preliminary analytical test result. To obtain a quantitative analytical result or to confirm positive results, a more specific alternate chemical method (e.g. LC/MS/MS) must be used. Clinical consideration and professional judgment should be applied to the interpretation of any drug-of-abuse test result.	The Psychemedics Cocaine assay is a radioimmunoassay (RIA) for the qualitative and semi-quantitative detection of cocaine in head hiar, leg hair, underarm hair and chest hair through the measurement of cocaine and cocaine metabolites at concentrations at or above a 5 ng/10 mg hair cutoff. For a quantitative analytical results or to confirm positive results *via* the presence of cocaine and cocaine metabolites, a more specific alternate chemical method must be used in order to obtain a confirmed analytical result.
510k	K111925	K010868
Measurand	Cocaine	Cocaine
Matrix	Human head or body hair	Human head or body hair
Cutoff concentration	5 ng cocaine/10 mg hair	5 ng cocaine /10 mg hair
Type of Test	Enzyme Immunoassay	Radioimmunoassay
Method of measurement	Microplate reader	Gamma counter
Extraction Method	NonproteolyticDigestion	Proteolytic Digestion
Confirmation Method	LC/MS/MS	LC/MS/MS

Summary of Performance Testing:

Precision Studies

Summary -Intra-Assay		
LEVEL	NEG	POS
B_0 (-100%)	15	0
-75%	15	0
-50%	15	0
-25%	15	0
plus 25%	0	15
plus 50%	0	15
plus 75%	0	15
plus 100%	0	15

Summary-Inter-Assay		
LEVEL	NEG	POS
B_0 (-100%)	75	0
-75%	75	0
-50%	75	0
-25%	75	0
plus 25%	0	75
plus 50%	0	75
plus 75%	0	75
plus 100%	0	75

Agreement Testing

Four hundred-twenty-five hair samples were assayed by the predicate device and by the Psychemedics Cocaine EIA. Four samples near the cutoff and positive with the predicate device were negative with the EIA device and by LC/MS/MS. The discordance between EIA and RIA was < 1%. Of the total samples, 15.8% were body hair samples.

	Negative by Predicate	**Positive by Predicate**
EIA Positive	0	126
EIA Negative	295	4

Two-hundred fifty-six of the samples were confirmed by LC/MS/MS, with the results shown in the following table.

LC/MS/MS:	**Zero**	**≥ 10% and <50% of Cutoff**	**≥ -50% of Cutoff and > Cutoff**	**≥ Cutoff, And < +50% of Cutoff**	**≥ +50% of Cutoff and < +100% of Cutoff**	**≥ +100% of cutoff**
EIA Positive	0	0	8	12	5	101
EIA Negative	118	9	3	0	0	0

Samples vary in the amount of contamination on the surface; in fact, contamination is, by its very nature, random in the way in which it may present on the hair sample. Therefore, it is not surprising that a sample might be positive in one screening assay and not in the next, even if the assays are the same technology. The samples were negative by LC/MS/MS, demonstrating that the EIA negative results, although discordant with the predicate, are correct.

Cosmetic Treatment Study

Twenty cocaine-negative hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences were

observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments.

Twelve cocaine-positive hair samples were treated with bleach, 12 with permanent wave, 12 with dye, 12 with relaxer, and 12 with shampoo, and the results compared to the same samples without the treatments. In each case of the 12 samples treated with a type of cosmetic treatment, 6 samples were treated with one brand of a particular product and 6 other samples with a second brand. The means and ranges of the EIA results of the 12 samples before and after the cosmetic treatments are shown in the table below. No positive samples became negative after the cosmetic treatments.

Treatment Status	Bleach	Dye	Perm	Relaxer	Shampoo
	Mean (Range) of B/B_0 x 100 Values of 12 Cocaine-Positive Hair Samples in Cocaine EIA				
Before	11.4 (2.9 – 19.2)	11.6 (2.9 – 22.5)	9.9 (2.9 – 17.6)	12.1 (4.2 – 26.0)	15.6 (2.9 – 54.6)
After	13.4 (3.0 - 18.8)	12.9 (2.8 – 30.9)	14.4 (6.8 – 24.8)	14.9 (4.9 – 29.8)	15.4 (2.7 – 57.4)

Contamination Study

Potential environmental contamination of samples that are identified as presumptive positive in the screening assay is addressed by an extensive washing procedure prior to confirmation and application of a wash criterion following confirmation, as described below.

Contamination of 8 hair samples by soaking in 1000 ng cocaine /mL of water resulted in a range of cocaine on the hair of 38.6 to 98.7 ng of cocaine /10 mg hair before washing. After washing by the procedure described below, the amount of cocaine remaining on the hair samples ranged from 1.1 to 3.0 ng/10 mg hair, with no samples at or above the cutoff even before application of the wash criterion.

Contamination of 8 hair samples by soaking in 1000 ng cocaine /mL of saline resulted in a range of cocaine on the hair of 8.5 to 29.3 ng of cocaine /10 mg hair before washing. After washing by the procedure described below, the amount of cocaine remaining on the hair samples ranged from 0.2 to 1.0 ng/10 mg hair, with all samples negative (i.e., below the cutoff) even without application of the wash criterion.

<u>The Wash Procedure</u>

a. Wash by Psychemedics' standard wash procedure:
    i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove isopropanol.
    ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0, containing 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
    iii. Repeat Step ii. two more times.
    iv. Add 2 mL of Wash Buffer, and shake in waterbath for 60minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
    v. Repeat Step iv. one more time. Remove Buffer. Save last wash buffer.
b. Analyze last wash for cocaine.

<u>Confirmation and Interpretation</u>

c. Perform confirmation procedures for cocaine and metabolites.
d. Calculate wash criterion:

i. Multiply the last wash value x 5.
ii. Subtract the value of the drug in the last wash from the value of the parent drug in the digested hair.
iii. If the result is less than the cutoff for the parent drug, the sample is interpreted as contaminated. If the result is ≥ the parent drug cutoff, in combination with other metabolite criteria, the sample is interpreted as positive due to ingestion. The parent-drug cutoff value for cocaine is 5 ng/ 10 mg hair.

Cross-reactivity and Interference Studies

Seven compounds, shown in the table below, showed cross-reactivity in the Cocaine assay. Seventy-nine other compounds showed no cross-reactivity in the assay. One-hundred-forty-one compounds tested for interference at +/-50% of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Cocaine EIA

Compound	Amount of Compound required to Produce a positive test at the cutoff of 5 ng cocaine/10 mg hair	Percent Cross-reactivity*
Benzoylecgonine	80	6.3
Norbenzoylecgonine	200	2.5
Norcocaine	8.0	62.5
Norcocaethylene	11	45.5
Cocaethylene	6.5	76.9
Benzoylecgonine Isopropyl ester	9	55
Tropacocaine	13	38.5

Stability of Calibrator and Control Solutions

The cocaine calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability of cocaine in methanol in the presence of other drugs of abuse was shown to exceed 1 year.

Recovery Study

Recovery of cocaine and benzoylecgonine from hair of cocaine users was shown to be substantially equivalent to that of the predicate device.

Conclusion:

The Psychemedics Microplate EIA for Cocaine in Hair is substantially equivalent to the predicate device K010868, and the results are substantially equivalent to LC/MS/MS results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAY - 1 2012

Re: k111925
Trade/Device Name: Psychemedics Microplate EIA for Cocaine in Hair
Regulation Number: 21CFR 862.3250
Regulation Name: Enzyme Immunoassay, Cocaine and Cocaine metabolites
Regulatory Class: Class II
Product Code: JXO
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k111925

Device Name: Psychemedics Microplate EIA for Cocaine in Hair

Indication For Use:

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The Psychemedics Microplate EIA for Cocaine in Hair provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgment should be applied to the interpretation of any drug-of-abuse test result.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111925